



# COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

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This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

## LATEST KEY DEVELOPMENTS

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- European Commission adopts revised antitrust Informal Guidance Notice on Novel Questions
- European Commission enhances eLeniency tool
- European Commission adopts Guidelines on collective agreements by solo self-employed people
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### Cybersecurity, Privacy & Data Protection

- European Commission publishes proposed Revised Product Liability Directive and proposed AI Liability Directive

## COMPETITION & STATE AID

### Competition

#### **European Commission withdraws Antitrust COVID Temporary Framework (see [here](#))**

On 3 October 2022, the Commission announced the withdrawal of the Antitrust COVID Temporary Framework, adopted in April 2020 (see *Commission Communication on the Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak* ([here](#))).

To recall, the Temporary Framework sought to enable the Commission to assess business cooperation projects in response to urgent situations arising from the pandemic (see also *Jones Day COVID-19 Update No. 3 of 10 October 2020*). In this context, the Commission could issue “comfort letters” concerning a specific cooperation project aimed at preventing shortages of critical hospital medicines. For instance, on 25 March 2021, the European Commission issued a “Comfort letter: Cooperation at a Matchmaking Event – Towards COVID19 vaccines upscale production” (see *Jones Day COVID-19 Update No. 42 of 31 March 2021*).

In withdrawing the Temporary Framework, the Commission indicated its view that, at this time, exceptional circumstances were no longer present that could trigger the need for companies to cooperate in order to mitigate the effects of the pandemic.

However, if the sanitary situation unexpectedly deteriorates, disrupting supplies of essential goods and services, the Commission further advises that companies can seek guidance under the revised Informal Guidance Notice (see *below on revised antitrust Informal Guidance*).

#### **European Commission adopts revised antitrust Informal Guidance Notice on Novel Questions (see [here](#))**

On 3 October 2022, the Commission issued a revised Informal Guidance Notice, replacing the 2004 Commission Notice on informal guidance relating to novel questions concerning Articles 81 and 82 of the EC Treaty that arise in individual cases (guidance letters) (see [here](#)).

The revised Informal Guidance Notice aims at providing more flexible conditions and enhanced legal certainty for businesses seeking guidance when assessing the legality of their actions under EU competition rules in cases presenting novel or unresolved questions, including in situations of crisis or other emergencies (see *above on withdrawn Antitrust COVID Temporary Framework*). In particular, the revised Informal Guidance:

- Increases the Commission's flexibility to address a broader range of issues in guidance letters. The Commission may, in particular, factor in the relevance of practices at issue in responding to the Commission's priorities and EU's interests; and
- Expands the definition of “novel” issues where there is “no clarification” available in the EU legal framework to address cases where there would be “no sufficient clarification”.

However, as in the 2004 Informal Guidance Notice, the Commission will

ordinarily not consider certain requests for guidance. For example, the Commission will not consider hypothetical questions and will not issue guidance letters on agreements or unilateral practices that the parties no longer implement. Undertakings may, however, present a request for a guidance letter to the Commission in relation to questions raised by an agreement or unilateral practice that they envisage. In such case, planning must have reached a sufficiently advanced stage for a request to be considered.

The accompanying Staff Working Document on the Stakeholder Consultation provides further information on the revised Informal Guidance (see [here](#)).

**European Commission enhances eLeniency tool (see [here](#) and [here](#))**

On 30 September 2022, the Commission announced upgrades to the eLeniency tool to facilitate secure online access to Commission documents by companies who are parties to cartel and antitrust proceedings.

The eLeniency tool, established in March 2019, enables companies and their legal representatives to submit statements and documents online as part of leniency, settlement and non-cartel cooperation proceedings. During the COVID-19 lockdown period, the Commission notes that the eLeniency tool ensured the smooth running of its leniency program.

The upgraded eLeniency system now provides for two-way communications between parties and the Commission, such that the Commission can now securely display documents online. Thus, parties no longer need to come to the Commission's physical premises to access or to be notified of a range of documents and information produced during leniency, cartel settlement and non-cartel cooperation proceedings.

According to the Commission, the eLeniency system provides the same guarantees in terms of confidentiality and legal protection as the traditional procedure of dictating oral corporate statements or receiving access/notification of case documents at the Commission's premises.

The Commission further reports that since its introduction in March 2019, the eLeniency tool has largely replaced the former practice of dictating oral corporate statements at the Commission's premises in Brussels.

**European Commission adopts Guidelines on collective agreements by solo self-employed people (see [here](#))**

On 29 September 2022, the Commission adopted Guidelines on the application of Union competition law to collective agreements regarding the working conditions of solo self-employed persons.\*

The Guidelines note that the COVID-19 crisis increased the vulnerability of many solo self-employed persons, as their loss of earnings was exacerbated by weak or non-existent national social security schemes and dedicated support measures.

The Guidelines clarify when solo self-employed persons can negotiate collectively to improve their working conditions without breaching EU competition rules. In particular, the Guidelines specify that:

- Competition law does not apply to solo self-employed persons who are in a situation comparable to workers, including solo self-

employed people who: (i) provide services exclusively or predominantly to one undertaking; (ii) work side-by-side with workers; and (iii) provide services to or through a digital labor platform.

- The Commission will not intervene in certain categories of collective agreements made by solo self-employed people who have insufficient bargaining power (e.g., when negotiating with economically stronger companies).

The Commission will monitor application of the Guidelines at national level and will review the Guidelines by 2030.

The accompanying Q&A provides further details on the Guidelines (see [here](#)).

*\* Under the Guidelines, “solo self-employed” persons are those without an employment contract or who are not in an employment relationship, and who rely primarily on their own personal labor to provide services. Such solo self-employed persons are working entirely on their own and not employing others.*

## State Aid

### **European Commission approves further schemes under Ukraine Temporary Crisis Framework (see [here](#))**

The Commission continues to approve additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine.

The Crisis Framework, adopted by the Commission on 23 March 2022, sets out the criteria for Member States to support businesses in the context of Russia's invasion of Ukraine and its serious disruption to the EU economy (see [Jones Day COVID-19 Update No. 80 of 25 March 2022](#)).

To recall, in adopting this Crisis Framework, the Commission noted that the conflict had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine.

Among the latest schemes under the Crisis Framework (until 3 Oct 2022):

- €800 million Greek scheme to support non-household electricity consumers in context of Russia's war against Ukraine
- €2 billion Italian guarantee scheme for the reinsurance of natural gas and electricity trade credit risk in context of Russia's war against Ukraine
- €700 million Italian scheme to support companies in context of Russia's war against Ukraine
- €300 million Walloon aid scheme to support businesses in context of Russia's invasion of Ukraine

Notably, the Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be

cumulated with aid granted under the COVID-19 Temporary Framework, provided that their respective cumulation rules are respected.

The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2022. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether it should be prolonged.

## TRADE / EXPORT CONTROLS

### **European Commission publishes report on implementation of Single Market Transparency Directive (see [here](#))**

On 26 September 2022, the European Commission published the Report on implementation of the Single Market Transparency Directive (SMTD),\* covering the period 2016-2020.

The SMTD, to recall, requires Member States to notify the Commission of their drafts technical rules on products and information society services prior to their adoption, while allowing the Commission and other Member States to examine these in view of avoiding potential barriers to the Single Market. It also allows businesses to examine and comment on these draft national technical rules.

According to the Report, the notification of draft national technical regulations continues to serve as a significant tool to address the emergence of barriers to trade and to ensure cooperation between the Commission and the Member States and among the Member States themselves. From 2016-2020, the Commission received 3,553 notifications.\*\*

On the COVID-19 crisis, the Report indicates that the SMTD's notification procedure played a vital role in managing the pandemic, which disrupted global supply chains and threatened the Single Market's integrity and the production/distribution value chains needed to supply the EU's health systems. The Report explains:

- In 2020, confronted by the COVID-19 pandemic, some Member States adopted or prepared national measures affecting the free movement of personal protective equipment and medicines. Such measures disrupted logistics and distribution chains and led to stockpiling responses in the supply chain.
- The Commission urged Member States to notify such COVID-19 related measures through the SMTD mechanism. These measures were assessed as a matter of high priority, and the Commission guided Member States in correcting those measures that could impede the free movement of essential goods in the Single Market.
- For measures notified after their adoption (some 150 COVID-19-related notifications in 2020), the SMTD notification mechanism still enabled information and peer-review through the TRIS communication platform, where Member States could be informed of COVID measures adopted by other Member States.

In announcing the Report's release, the European Commission also recalled other initiatives to promote Single Market transparency and Member State cooperation, including its recently proposed Regulation for a Single Market

Emergency Instrument (see [Jones Day COVID-19 Update No. 87 of 4 October 2022](#)) and the work of the Single Market Enforcement Taskforce (see below).

*\* Directive (EU) 2015/1535 of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (see [here](#)).*

*\*\* In view of ensuring transparency, all national measures (and the Commission and Member State contributions responding to these) are publicly available on the Technical Regulations Information Service (TRIS) database (see [here](#)).*

**Single Market Enforcement Taskforce meeting (see [here](#))**

On 26 September 2022, the Single Market Enforcement Taskforce gathered members of the European Commission and Member States to discuss barriers in the Single Market and solutions to overcome these.

To recall, the Taskforce was created in 2020 to provide a key forum to remove barriers introduced by Member States during the COVID pandemic to ensure the availability of essential medical supplies and protective equipment in Europe.

At the meeting, the Taskforce reported on the results of current projects, such as the prior checks and document requirements for recognizing professional qualifications, which the Commission considers as all the more important in the context of the post-pandemic Single Market for services.

The European Commission presented, in particular, several best practices of Member States to streamline administrative requirements for cross-border service providers (e.g., the use of modern electronic tools to exchange documents, and to reduce the administrative burden for businesses).

The Taskforce regularly informs of its progress to the Competitiveness Council (Council of the EU) and the European Parliament's Internal Market and Consumer Protection Committee.

**DG Trade publishes Statistical Guide 2022 (see [here](#))**

On 8 September 2022, the European Commission Directorate-General for Trade released the Statistical Guide 2022.

The Guide contains selected figures outlining the current state of and recent developments in EU foreign trade (i.e. trade with the rest of the world), including statistics on trade in goods, services, and foreign direct investment.

In particular, the Guide notes that in 2021, foreign trade at the worldwide level started recovering from the significant shock caused by COVID-19 in 2020, when world trade fell by nearly 10% for goods and by over 20% for services.

The Guide indicates that in 2021, the EU remained the world's leading trader of goods and services, with imports and exports together accounting for some 16.2% of world trade:

- Total trade in goods (imports and exports) amounted to €4.3 trillion (compared to €3.7 trillion in 2020).
- Total trade in services (imports and exports) amounted to nearly €2 trillion (compared to €1.8 trillion in 2020)

Further information on the Guide and its methodology can be obtained from DG Trade's Statistics desk ([trade-statistics@ec.europa.eu](mailto:trade-statistics@ec.europa.eu)).

## MEDICINES AND MEDICAL DEVICES

### Remarks on European Health Union by European Commissioner for Health and Food Safety (see [here](#))

On 3 October 2022, European Commissioner for Health and Food Safety, Stella Kyriakides gave opening remarks to the European Parliament Plenary Joint Debate on the European Health Union.

The Plenary Joint Debate was held in view of voting on adopting (i) the proposed Regulation on serious cross-border threats (see also [Jones Day COVID-19 Update No. 86 of 8 September 2022](#)) and (ii) the proposed Regulation extending the mandate of the European Centre for Disease Prevention and Control (ECDC) (see also [Jones Day COVID-19 Update No. 70 of 6 December 2021](#)).

Both proposed Regulations are viewed as key components to building the European Health Union and intend to ensure stronger preparedness and coordination at EU level to tackle current and future health crises.

As recalled by Commissioner Kyriakides, both proposed Regulations fit alongside other key pieces of legislation for reinforcing the European health security framework, as explained in the Commission Communication on Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats of 11 November 2020, which drew on lessons from the COVID-19 crisis (see also [Jones Day COVID-19 Update No. 27 of 18 November 2020](#)).

On the proposed Regulation on serious cross-border threats, Commissioner Kyriakides remarked that it *"paves the way for a stronger EU role in preventing, preparing and managing health threats."*

On the proposed Regulation extending the mandate of the ECDC, Commissioner Kyriakides emphasized that *"the ECDC has been essential in making sense of and managing the pandemic. With a stronger focus, we will be better prepared for the future."*

Commissioner Kyriakides also praised the European Parliament for its role in securing key elements in both draft Regulations (e.g. provisions on joint procurement of medical countermeasures; inclusion of "prevention" alongside response and preparedness activities; and ensuring Member States reporting on stocks of critical medical countermeasures).

Additionally, Commissioner Kyriakides mentioned that the Commission maintained some institutional concerns on both texts and would issue statements on these points accordingly.

### HERA secures additional treatment courses and vaccines to treat and prevent Monkeypox (see [here](#) and [here](#))

On 26 September 2022, the European Health Emergency Preparedness and Response Authority (HERA) announced that it had secured over 10,000 antiviral treatment courses to treat Monkeypox. This follows the 170,920 vaccines doses secured by HERA against the outbreak, as announced on 7 September 2022, adding to the over 330,000 vaccines already purchased by the EU.

The Commission has emphasized the importance of recalling the lessons learned from the COVID-19 pandemic, including during the ongoing work on the monkeypox outbreak (see [here](#)).

European Commissioner for Health and Food Safety, Stella Kyriakides stated that the Monkeypox treatment courses and vaccines “*will help Member States meet immediate needs and ensure care for more patients in Europe. The declining trend of Monkeypox cases in the EU is encouraging but it does not mean that the threat has passed or that we can lower our guard. Preparedness is [fundamental to] our European Health Union.*”

These types of measures are part of HERA's first Work Plan 2022 (see [Jones Day COVID-19 Update No. 77 of 23 February 2022](#)) and contribute, in particular, to providing timely and appropriate responses to health crises.

The treatment courses were funded by HERA and will be channeled via rescEU (part of the European Civil Protection Mechanism), whose strategic reserves will be available to Member States on an urgent needs-basis.

The vaccine doses were purchased by HaDEA (Commission's Health and Digital Executive Agency) on behalf of HERA, which will be responsible for making the vaccine doses available to EU Member States, Norway and Iceland.

The Commission recognizes that these measures constitute an emergency procurement to ensure that urgent needs are met. Additionally, ongoing joint procurement driven by HERA and EU Member States will also address the medium and longer-term needs of Member States.

## CYBERSECURITY, PRIVACY & DATA PROTECTION

**European Commission publishes proposed Revised Product Liability Directive and proposed AI Liability Directive (see [here](#) and [here](#))**

On 28 September 2022, the Commission published the (i) proposed Directive on liability for defective products (Revised Product Liability Directive) and (ii) proposed Directive on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive).

The two proposals seek to adapt liability rules to the green and digital transition within the EU (see *Jones Day Alert, [European Commission Proposes New Liability Rules on AI and Products, September 2022](#)*). In particular, with the COVID-19 pandemic and the implementation of social-distancing measures by authorities around the world, the use of artificial intelligence (AI) technologies increased significantly. At the same time, liability is amongst the top three barriers to the use of AI by European companies (along with data standardization and regulatory obstacles), as noted in the proposed AI Liability Directive.

The **proposed Revised Product Liability Directive** aims at modernizing the current EU framework (nearly 40 years old) on manufacturers' liability for defective products in view of covering all products sold in the EU, for example, by seeking to:

- Adapt liability rules to the reality of products in the digital age, by allowing compensation for damages caused by, e.g., AI systems, digital services, or cybersecurity vulnerabilities;

- Adapt liability rules to circular economy business models, in line with EU efforts to achieve sustainability and waste reduction goals, by clarifying when economic operators can be held liable when substantially modifying or upgrading products, such as by modifications through changes to software;
- Facilitate compensation claims by requiring manufacturers to disclose necessary information in court and easing the burden of proof for victims in more complex cases, such as those involving pharmaceuticals, smart products, or AI-enabled products.

Furthermore, in line with the proposal's objectives, compensation is allowed for damage caused by "*loss or corruption of data that is not used exclusively for professional purposes*".

The **proposed AI Liability Directive** provides for a targeted harmonization of national AI civil liability rules aimed at increasing legal certainty and fostering AI innovation. It will apply to non-contractual civil claims for damages caused by all types of AI systems.

The proposal supplements the proposed Revised Product Liability Directive by introducing two main additional measures specifically for AI:

- Alleviating victims' burden of proof through a rebuttable "presumption of causality", whereby courts can establish the causal link between the damage and the AI system providers' breach of a certain obligation relevant to the harm under EU or national law, where proven by the victim. In this respect, depending on each Member State's civil law system, victims could claim compensation for damage caused to various legal interests, such as those appearing in the EU Charter of Fundamental Rights (e.g., right to life (Article 2) and the right to private and family life (Article 7)); and
- Empowering courts to order providers of high-risk AI systems to disclose relevant information, subject to appropriate safeguards to preserve the legitimate interests of all parties, such as trade secrets or other sensitive information.

Further information on the proposals is provided in the Commission's accompanying Q&As (see [here](#) and [here](#)).

The Commission's proposals will now be examined by the European Parliament and the Council of the EU.

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